

[en Español \(http://esp.fda.gov/TobaccoProducts/default.htm\)](http://esp.fda.gov/TobaccoProducts/default.htm)

# Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)

Vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or ecigs), and e-pipes are some of the many terms used to describe electronic nicotine delivery systems (ENDS).

These products use a liquid “e-liquid” that may contain nicotine, as well as varying compositions of flavorings, propylene glycol, vegetable glycerin, and other ingredients. The liquid is heated into an aerosol that the user inhales.

ENDS may be manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble pens or other everyday items. Larger devices, such as tank systems or mods, bear little or no resemblance to cigarettes.

**[Share comments, data, research results, or other information about flavors in tobacco products \(https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products\)](https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products)**

On March 20, 2018, FDA issued an advance notice of proposed rulemaking to help determine how best to regulate flavors in tobacco products, including menthol. This action creates an opportunity for public comment as first announced in FDA's **[comprehensive plan for tobacco and nicotine regulation \(TobaccoProducts/NewsEvents/ucm568425.htm\)](https://www.fda.gov/NewsEvents/ucm568425.htm)** on the role of flavors in tobacco product use and use patterns.

On this page, you can find:

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- **[FDA Regulation of Electronic Nicotine Delivery Systems and E-Liquids](#)**
- **[Manufacturing Electronic Nicotine Delivery Systems and E-Liquids](#)**
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- **[Retail Sales of Electronic Nicotine Delivery Systems and E-Liquids](#)**
  - **[Vape Shops That Mix E-Liquids or Modify Products](#)**
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## Statistics about Electronic Nicotine Delivery System Use

- More than 2 million middle and high school students were current users of e-cigarettes in 2016.<sup>1,2</sup>
- 11% of high school and 4.3% of middle school students were current users of e-cigarettes in 2016.<sup>1</sup>
- E-cigarette use rose from 1.5% to 16.0% among high school students and from 0.6% to 5.3% among middle school students from 2011 to 2015.<sup>1</sup>
- In 2013-2014, 81% of current youth e-cigarette users cited the availability of appealing flavors as the primary reason for use.<sup>3</sup>



## FDA Regulation of Electronic Nicotine Delivery System

In 2016, FDA finalized a rule extending CTP's regulatory authority to cover all tobacco products, including electronic nicotine delivery systems (ENDS) that meet the definition of a tobacco product. FDA now regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories. Examples of components and parts of ENDS include:

[/ucm/groups/fdagov-public/documents/image/ucm541368.jpg](https://www.fda.gov/ucm/groups/fdagov-public/documents/image/ucm541368.jpg)

- E-liquids
- A glass or plastic vial container of e-liquid
- Cartridges
- Atomizers
- Certain batteries
- Cartomizers and clearomizers
- Digital display or lights to adjust settings
- Tank systems
- Drip tips
- Flavorings for ENDS
- Programmable software

However, products marketed for therapeutic purposes (for example, marketed as a product to help people quit smoking) are regulated by the FDA through the Center for Drug Evaluation and Research (CDER). FDA published a [rule clarifying the jurisdiction over tobacco products, drugs, and devices](#) ([/TobaccoProducts/Labeling/RulesRegulations/Guidance/ucm462957.htm](#)).

### Manufacturing Electronic Nicotine Delivery Systems and E-Liquids

If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must [comply with these requirements for manufacturers](#) ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm](#)).

CTP's Office of [Small Business Assistance](#) ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm](#)) can answer specific questions about requirements of small businesses and how to comply with the law. This office also provides online educational resources to help regulated industry understand FDA regulations and policies.



### Required Nicotine Addictiveness Warning on Packages and Advertisements

Beginning in 2018, all newly-regulated ["covered"](#) ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm514344.htm](#)) tobacco products\* must bear the [required nicotine addictiveness warning statement](#) ([/TobaccoProducts/Labeling/Labeling/ucm524470.htm](#)) on product packages and advertisements. \*Note: [Cigars](#) ([/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482562.htm](#)) also have additional required warning statements.

### Retail Sales of Electronic Nicotine Delivery Systems and, E-Liquids

[Order FDA Rules for ENDS Sales Flyer](#)



[\(/downloads/TobaccoProducts/AboutCTP/UCM580536.pdf\)](#)

[Order Print Copies \(https://digitalmedia.hhs.gov/tobacco/print\\_materials/RE-05\)](https://digitalmedia.hhs.gov/tobacco/print_materials/RE-05)

If you sell ENDS, e-liquids, or their components or parts made or derived from tobacco, please read this [summary of federal rules that retailers must follow](#)

[\(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm\)](#).

You may also [order flyers \(https://digitalmedia.hhs.gov/tobacco/\)](https://digitalmedia.hhs.gov/tobacco/) with rules for electronic nicotine delivery system sales or download a PDF to print yourself.

You can find a list of retailer responsibilities for ENDS in the final rule [Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act \(https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to\)](https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to). In addition, our website offers more information on [regulations, guidance, and webinars for retailers](#)

[\(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237759.htm\)](#).

### Vape Shops That Mix E-Liquids or Modify Products

If you operate a vape shop that mixes or prepares liquid nicotine or nicotine-containing e-liquids, or creates or modifies any type of ENDS, you may be considered a manufacturer. As a result, some vape shops may have legal [responsibilities as both manufacturers and retailers](#)

[\(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm514606.htm\)](#) of tobacco products. Please also see the [Draft Guidance: Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops](#)

[\(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm536995.htm\)](#).

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## Importing Electronic Nicotine Delivery Systems and E-Liquids

Tobacco products [imported or offered for import \(/TobaccoProducts/Labeling/ucm290823.htm\)](/TobaccoProducts/Labeling/ucm290823.htm) into the United States must comply with all the applicable requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

You can also learn more about the importation process in the [FDA Regulatory Procedures Manual, Chapter 9, Import Operations and Actions \(/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179264.htm\)](/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179264.htm).

If you have questions about importing a specific tobacco product, please [contact the FDA district into which your product will be imported \(/downloads/ICECI/Inspections/IOM/UCM123522.pdf\)](/downloads/ICECI/Inspections/IOM/UCM123522.pdf) (PDF - 406 KB).

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## Report a Problem with a Tobacco Product or Potential Tobacco Product Violations

If you have experienced an unexpected health or safety issue with a specific tobacco product, you can [report a problem \(/TobaccoProducts/PublicHealthScienceResearch/ucm377563.htm\)](/TobaccoProducts/PublicHealthScienceResearch/ucm377563.htm) with any tobacco product, including vapes, to the FDA. Knowledge about adverse experiences can help the FDA identify health or safety issues beyond those normally associated with product use.

If you believe these products are being sold to minors, or you see another potential violation of the FD&C Act or FDA's tobacco regulations, [report the potential violation \(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm330160.htm\)](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm330160.htm).

You can [read the adverse experience reports for tobacco products \(/TobaccoProducts/AboutCTP/ucm221165.htm\)](/TobaccoProducts/AboutCTP/ucm221165.htm) to FDA in the FOIA Electronic Reading Room.

**1. Consider using vapes with safety features**  
such as firing button locks, vent holes, and protection against overcharging.

**2. Keep your vape covered.**  
Don't let it come into contact with coins or loose batteries in your pocket.

**3. Never charge your vape with a phone or tablet charger.**  
Always use the charger that came with it.

**4. Don't charge your vape overnight**  
or leave it charging unattended.

**5. Replace the batteries if they get damaged or wet.**  
If your vape gets damaged and the batteries are not replaceable, contact the manufacturer.

Labels in diagram: Atomizer, Fire Button Lock, Fire Button, Battery Vent Holes, Battery Cover, Atomizer Connector, USB Port.

[\(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm539362.htm\)](https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm539362.htm)

## References

## Additional Resources

- **Small Business Assistance**  
([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm](https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm))
- **Manufacturing** ([/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm](https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm))

- **[Summary of Federal Rules for Tobacco Retailers](/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm)**  
(/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm)
- **[Tips to Help Avoid "Vape" Battery Explosions](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm539362.htm)**  
(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm539362.htm)
- **[FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products](/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm)**  
(/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm)

**[More in Products, Ingredients & Components](/TobaccoProducts/Labeling/ProductsIngredientsComponents/default.htm)**  
(/TobaccoProducts/Labeling/ProductsIngredientsComponents/default.htm)

**[Cigarettes](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482563.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482563.htm)

**[Chemicals in Cigarettes: From Plant to Product to Puff](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm535235.htm)**  
(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm535235.htm)

**[Cigars, Cigarillos, Little Filtered Cigars](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482562.htm)**  
(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482562.htm)

**[Dissolvable Tobacco Products](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482569.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482569.htm)

**[Flavored Tobacco](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm)

**[Harmful and Potentially Harmful Constituents \(HPHCs\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20035927.htm)**  
(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20035927.htm)

**[Hookah Tobacco \(Shisha or Waterpipe Tobacco\)](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482575.htm)**  
(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482575.htm)

**[Menthol Cigarettes](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20038740.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm20038740.htm)

**[Nicotine Gels](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482571.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482571.htm)

**[Pipe Tobacco](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482580.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482580.htm)

**[Roll-Your-Own Tobacco Products](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482581.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482581.htm)

**[Smokeless Tobacco Products](/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482582.htm)** (/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm482582.htm)

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(/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm)